K083637
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APR 20 2009

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer

DEVICE NAME

Trade/Proprietary Name:	Calix ™ Spinal Implant System
Common Name:	Intervertebral body fusion device

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified intervertebral fusion device with bone graft, cervical as a Class II device (21 CFR 888.3080). The product code for intervertebral fusion device with bone graft, cervical is ODP. Additionally, the FDA has classified spinal vertebral body replacement device as a Class II device (21 CFR 888.3060). The product code for spinal vertebral body replacement device is MQP. These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

When used as a vertebral body replacement, the X-spine Calix System is intended for use in the thoracic and/or thoracolumbar spine (TI-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e. partial or total vertebrectomy procedures) due to tumor or trauma (i.e. fracture). The Calix device, when used as a vertebral body replacement, can be packed with either allograft or autograft.

When used as an intervertebral body fusion device, the X-spine Calix System is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should receive 6 weeks of non-operative treatment prior to treatment with the Calix intervertebral body fusion device.

For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical, thoracic or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

DEVICE DESCRIPTION

The Calix system is a generally box-shaped device with various holes located throughout its geometry and teeth on the superior and inferior surfaces. The device is made from polyetheretherketone (Invibio PEEK-Optima).

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Calix Spinal Implant System is substantially equivalent in indications and design principles to predicate devices.

PERFORMANCE DATA

Mechanical testing indicates that the Calix system is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

X-Spine Systems, Inc.
% David Kirschman, M.D.
452 Alexandersville Road
Miamisburg, Ohio 45342

APR 20 2009

Re: K083637
Trade/Device Name: Calix Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: February 2, 2009
Received: April 8, 2009

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A
Indications for Use – REVISION 2

510(k) Number (if known): K083637

Device Name: Calix™ Spinal Implant System

Indications for Use:

When used as a vertebral body replacement, the X-spine Calix System is intended for use in the thoracic and/or thoracolumbar spine (TI-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e. partial or total vertebrectomy procedures) due to tumor or trauma (i.e. fracture). The Calix device, when used as a vertebral body replacement, can be packed with either allograft or autograft.

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For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical, thoracic or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083637